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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,544	10/26/2001	Steve A. Herweck	ATA-333	2463
959	7590	09/21/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/045,544		HERWECK ET AL.	
	Examiner		Art Unit	
	Julian W. Woo		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40, 56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-26, 29-36, 38-40, 56 and 57 is/are rejected.
- 7) ☒ Claim(s) 22, 27, 28 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2004 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first passage of the first leg and the second passage of the second leg are said to be in fluid communication with organs, which are unpatentable parts of the human body cited as structural parts of the invention (i.e., organs are cited as if they are parts of the invention).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 6-9, 11, 13-21, 23-26, 30-32, 34, 36, and 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Kawamura (6,524,273). Kawamura discloses, in figures 2, 9, and 10, a body fluid cartridge exchange platform device (10) or access device, where the device includes, inter alia, a hollow tubular platform housing (40) with first and second ends (46 and 44 or 52 and 50) and respectively, first and second openings or first and second ports at the ends, which facilitate bi-directional installation and removal of inserts regardless of which opening inserts are installed through; an arcuate flow path (48 or 54), tubular cartridge inserts (68, 70) or cartridges insertable and removable through the first and second openings and be used for drug delivery, each having a flow path leading to the arcuate flow path; first and second hollow leg members (72, 74 and/or 12, 14) with internal lumens, channels with channel ports, or external communicating passageways (72, 74); a microporous cell penetratable cuff (32, see col. 3, lines 35-40); a locking mechanism (62) or flexible tab for each of the tubular cartridge inserts (see col. 4, lines 48-50); and a marking disposed on the platform housing (56); where each of the cartridge tubular inserts provides a flow path having a diameter that varies from a diameter relatively greater than an internal diameter of the first hollow leg member (72 or 74) to substantially the same diameter as

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the internal diameter of the first hollow leg member; where the first and second legs penetrate the skin of a patient or minimally invasively implanted in a patient, and where the channels complete a flow path between first and second passages through first and second ports (via the dialyzer).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 10, 33, 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura. Kawamura discloses the invention substantially as claimed, but does not disclose first and second legs, each having a diameter of less than 10mm; nor does Kawamura disclose a cartridge insert tool. Nevertheless, it would

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have been a matter of design choice to size each of the first and second legs at a diameter of less than 10mm. The choice would be dependent upon the size of the lumen of the artery or vein in which a leg is implanted and upon the desired rate of blood flow through the leg. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to apply a common, surgical tool, such as a forceps, as a cartridge insert tool. Forceps would provide a convenient means to grip and manipulate a cartridge for insertion and removal through a hollow tubular platform housing.

8. Claims 12 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawamura in view of Santerre et al. (5,798,115). Kawamura discloses the invention substantially as claimed, but does not disclose a bioactive coating disposed on at least a portion of the flow path between the first and second hollow leg members and through the tubular cartridge insert. Santerre et al. teach bioactive coatings for various implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Santerre et al., to include bioactive coating disposed on at least a portion of the flow path of Buselmeier's device. Such a coating would reduce infections caused by the presence of access devices in a patient's body.

Allowable Subject Matter

9. Claims 22, 27, 28, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses an access device with, inter alia, a housing having first and second openings, first and second hollow leg members extending from the housing, and cartridges, where the first leg extends in a staggered and divergent manner from the second leg with respect to the housing, where the housing has a generally oval cross-section; and where a cartridge has first and second channel ports at opposite ends of the channel within the cartridge, where a distance between the first channel port and a first end of the cartridge is greater than a diameter of the first channel port.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. Applicant's arguments with respect to claims 1-40, 56, and 57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kawamura (6,231,541) teaches an access device with a housing and cartridge.

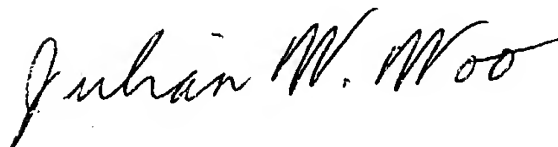
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-

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0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 17, 2004